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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,319	08/06/2003	Benjamin Garden	MSDI-67/PC933.00	8113
52196	7590	12/10/2007		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,319

Applicant(s)

GARDEN ET AL.

Examiner

James L. Swiger

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/6/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (US Patent 6,193,721). Michelson discloses a spinal stabilization system positionable along the spinal column, a holding element (60) that includes a distal portion (towards the plate) and proximal portion (92) (56) and an intermediate portions (90/62) therebetween that also has an instrument first engaging portion (considered as 64/65) that is adapted to receive a rotational force from a second portion (68) that is spaced from a first portion adapted to receive a force. It may also be considered to have a 'distally oriented' engagement surface. The proximal and distal elements are also in cooperation with the auxiliary portion maintain a position along the spine. The retaining device also has a penetrating element (66) that fits into acannulation with a central aperture (Fig. 32) that also aligns with the aperture of a stabilization system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Patent 6,193,721) in view of Konieczynski et al. (US Patent 7,175,624). Michelson discloses a spinal stabilization system positionable along the spinal column having at least an auxiliary element mounted thereto (see Figs. 21, 29, 18, or item 20) and wherein the auxiliary element has a hole or cannulation (208/24), a holding element (60) that includes a distal portion (towards the plate) and proximal portion (92) (56) and an intermediate portions (90/62) therebetween that also has an instrument first engaging portion (considered as 64/65) that is adapted to receive a rotational force from a second portion (68) that is spaced from a first portion adapted to receive a force. It may also be considered to have a 'distally oriented' engagement surface. The proximal and distal elements are also in cooperation with the auxiliary portion maintain a position along the spine. The retaining device also has a penetrating element (66) that fits into a cannulation with a central aperture (Fig. 32) that also aligns with the aperture of a stabilization system.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson '721 in view of Kuslich et al. (US Publication 2003/0083749). Michelson discloses the claimed invention except for the teaching of the use of the device as a corpectomy implant. Kuslich et al. teaches the use of a stabilization system that is, more

specifically, a corpectomy device (pars. 0030 through 0035). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Michelson that may also be used as a Corpectomy device in view of Kuslich et al. to better use the device to stabilize the spine.

As a general note, Michelson discloses each and every element as required by applicant's claims. However, Michelson does not disclose, specifically the use of some kind of device that has a distal portion that goes through the claimed auxiliary element, particularly the distal portion of the a holding device going through the cannulation of the auxiliary element. Michelson does, however, teach the use of a distal element coming into contact with the spine to help secure the stabilization system (see Figs. 31 and 33 and Col. 23 lines 18-40). Michelson teaches a similar use, except the distal point goes through the hole in the plate itself, and not through the aux element. Further Michelson teaches that the distal portion of the holding element is configured (Fig. 32, 71) so that it can grab the plate or screw and provide rotation. In view of this, the above claims are rejected as obvious over re-arrangement of parts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to put the distal end through a different location (one hole versus another), since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Additionally, Michelson discloses the claimed invention except for the above teaching related to relocation of the distal portion. Konieczynski et al. discloses a spinal device that has an auxiliary element 170 through which a distal element may pass (64,

and fig. 1a). This member helps to better lock the plate into position (Col. 11, lines 28-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Michelson having the distal end of a fixation or pointed element in view of Konieczynski et al. to better install the spinal fixation plate.

Response to Arguments

Applicant's arguments submitted on 11/13/2007 are generally considered moot in light of the new rejections above. Clarifications have been edited with regard to an auxiliary element. See above for further details.

Finality

The Finality of the previous action dated 9/12/2007 has been withdrawn.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/635,319
Art Unit: 3733

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JLS

12/5/07



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER